
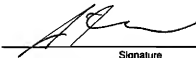


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 1001.2144102	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>SEPTEMBER 8, 2009</u> Signature <u></u> Typed or printed name <u>THU H. LE-TO</u>		Application Number 10/763,932 First Named Inventor GERALD HELLER Art Unit 3763 Filed JANUARY 23, 2004 Examiner QUYNH-NHU VU	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>41,376</u>		<u></u> Signature J. SCOT WICKHEM Typed or printed name 612.677.9050 Telephone number SEPTEMBER 8, 2009 Date	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input type="checkbox"/> Total of _____ forms are submitted.			

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	GERALD HELLER et al.	Confirmation No.:	7855
Serial No.:	10/763,932	Examiner:	Quynh-Nhu Vu
Filing Date:	JANUARY 23, 2004	Group Art Unit:	3763
Docket No.:	1001.2144102	Customer No.:	28075
Title:	ADJUSTABLE LENGTH CONVERSION ADAPTER FOR DILATATION CATHETERS		

PRE-APPEAL CONFERENCE BRIEF

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The undersigned hereby certifies that this paper(s), as described herein, is being electronically transmitted to the U.S. Patent and Trademark Office on the date shown below



Thu H. Le-To

SEPTEMBER 8, 2009

Date

Dear Sir:

Appellants have carefully reviewed the Final Office Action of May 8, 2009 and the Advisory Action of July 21, 2009. Currently, claims 10-13, 15-16, 18, 23-31 are believed to be pending in the application, claims 10-13, 15-16, 18, 23-30 have been twice rejected, and claim 31 has been withdrawn from consideration. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

As a preliminary matter, the Advisory Action of July 21, 2009 does not indicate the status of the amendments presented with the response of July 8, 2009. Pursuant to a conversation held between Appellant's representative, J. Scot Wickhen, and the Examiner, Quynh-Nhu Vu, on August 8, 2009, it is Appellants understanding that these amendments will be entered and that a supplementary Advisory Action so stating will be entered in the record. A supplementary

Advisory Action of August 12, 2009 appears to enter the amendment to the Figures, but leaves unaddressed the amendment to the specification and to the claims. Appellants are proceeding under the understanding that the amendments to the specification (which correspond to those in the Figures) and to the claims (which correct minor dependency issues) will also be entered once given due consideration, and ask that any contrary understanding be brought to their attention. Nevertheless, these amendments do not affect the merit of the anticipation or obviousness rejections, which will now be discussed.

Claims 10-12 and 23-30 were rejected under 35 USC 102(b) as anticipated by, or in the alternative, under 35 USC 103(a) as obvious over Stevens (U.S. Patent No. 4,798,586). Appellants respectfully appeal the rejection of these claims

Stevens pertains to a method and apparatus for aiding dilation catheterization that involves the insertion of an atherectomy device through a lumen of a balloon catheter. In contrast, the claims of the present invention are directed to an adjustable length conversion adapter for dilation catheters. As explained below, Stevens does not teach or suggest all the elements of claim 10, nor are the elements obvious over the atherectomy system of Stevens.

For example, Stevens does not appear to disclose an adapter as claimed. As recited in claim 10, the adapter is "selectively positionable within said lumen of said catheter, said adapter including an external diameter substantially equal to said internal diameter of said lumen of said catheter, said adapter further including a lumen defining an internal diameter substantially equal to said second external diameter of said second guidewire for fitting accommodation thereof." The Final Office Action of May 8, 2009 claims that elements 10b and 60 comprise the adapter. There are several areas where this characterization fails.

First, Stevens teaches that elements 10 and 10b define an air passageway 40 leading to balloon 11, where air passageway 40 is used to inflate the balloon. Stevens, column 3, lines 52-55 and Figure 5. The air passageway 40 is defined between intermediate catheter 10b and outer catheter 10. Therefore, intermediate catheter 10b cannot have an external diameter substantially equal to the internal diameter of catheter 10 without closing off this passageway and rendering the device inoperative.

Second, adapter 60 is bounded on both sides in Figure 7 by element 64 and it is clear from that figure that no external diameter of adapter 60 or alternate adapter 90 is substantially

equal to an internal diameter of catheter 10. The smallest part of adapter 60 fits in hub 46 and even that part is substantially larger than the inner diameter of catheter 10.

Thus it cannot be said that elements 10b and/or 60 of Stevens meets the language of claim 10 of "said adapter including an external diameter substantially equal to said internal diameter of said lumen of said catheter." Further, because such a modification would close off inflation lumen 40, there can be no motivation to make such a modification.

Claim 10 also recites "an adapter selectively positionable within said lumen of said catheter. Stevens fails to teach this element as well. Element 10b, as shown in Figure 5 is fixed within the lumen of catheter 10, being joined together at the distal end. Element 60 is not positionable within catheter 10 at all; it merely has a distal end threadably joinable with luer fitting 46.

Claim 10 also recites "a first guidewire having a first external diameter and a second guidewire having a second external diameter smaller than said first external diameter." In the Final Office Action, these elements are said to be anticipated by guidewire 20 and sleeve 64. The Office Action states that "a second wire 64 is considered as a guidewire having a second external diameter smaller than the first external diameter." Sleeve 64 is part of a drive catheter 30 which is "substituted for the guidewire 20." Col. 4, l. 10. Thus there is no teaching that element 64 has a smaller external diameter than guidewire 20. As they are intended to be substituted for one another in the same lumen, they presumably have the same external diameter. Stevens, in any case, is silent on the point.

Claim 10 also "a catheter including a lumen defining an internal diameter substantially equal to said first external diameter of said first guidewire for fitting accommodation thereof." The catheter of Stevens said to anticipate this catheter is catheter 10. However, as can be seen by reference to Figure 5, any guidewire having an external diameter substantially equal to that of the inner diameter of catheter 10 cannot fit within intermediate catheter 10b, which as discussed above, is fixed within catheter 10.

This is nearly all the language of claim 10. When one properly considers all words in the claim, it can readily be seen that Stevens does not anticipate claim 10, nor is claim 10 obvious over Stevens.

Independent claim 23 is likewise not anticipated by nor obvious over Stevens for similar reasons. For example, claim 23 recites “a first adapter having an outer diameter substantially equal to the inner diameter of the catheter and a first inner diameter.” As discussed above with respect to Figure 5 of Stevens, no such adapter is disclosed by Stevens nor obvious over it for the reason given above, namely, to modify the diameter of catheter 10b so that it is substantially equal to the inner diameter of catheter 10 eliminates inflation lumen 40.

Claim 23 also recites “a second adapter having an outer diameter substantially equal to the inner diameter of the catheter and a second inner diameter...wherein the second inner diameter is different from the first inner diameter.” The element said to correspond to the second adaptor is interior seal 80. There is no teaching in Stevens that interior seal 80 has an outer diameter substantially equal to the inner diameter of catheter 10. There is further no teaching in Stevens that the inner diameter of interior seal 80 is different from that of the first adapter (elements 10b and 60).

Therefore, when one properly considers all words in the claim, it can readily be seen that Stevens does not anticipate claim 23, nor is claim 23 obvious over Stevens.

Independent claim 27 is a method claim, directed to a method for configuring a catheter system. With respect to this claim, the Examiner argues “regarding claims 27-30, since the method of configuring or performing a catheter system is merely a list of steps of using configuring a catheter system, these steps must be performed to obtain the device (see rejection of claims 10-13, 15-18, 23-26 above). Therefore, the method for configuring a catheter system would be inherent to the shown structure of the device.”

This as a general matter is simply not true. Even supposing for the sake of argument that all of the physical components claimed in claim 27 were present in Stevens, there are many different methods one may use with particular components. To shown anticipated or obviousness over Stevens, one needs to show that the elements claimed in claim 27 are present in or obvious variations over Stevens, and one needs to show that those elements are used in a method as claimed (or that such a method would be obvious over Stevens). None of this was done in the Office Action, nor do Appellants believe that it can be done.

For example, claim 27 recites “wherein each of the plurality of adapters has an outer diameter substantially equal to the inner diameter of the catheter. As discussed above, Stevens

does not teach any adapters where the outer diameter is substantially equal to the inner diameter of the catheter. Further, Stevens does not teach a plurality of such adapters. Claim 27 also recites "selecting an adaptor from the plurality of adapters..." This is not taught or suggested by Stevens "Selecting" means picking out or choosing from among a number of alternatives. (see <http://onelook.com/?w=select&ls=a>) The various "adapters" of Stevens are components each of which has a particular location and function in the catheter system of Stevens. There is thus no selection when configuring the catheter of Stevens; there is mere assembly. For at least these reasons, appellants submit that claim 27 is also allowable over the cited prior art.

All the independent claims have been addressed above. The dependent claims are also believed allowable for at least the reason that each depends from one of the above independent claims and contains additional elements. The independent claims are also believed to be independently allowable over Stevens. For reasons of limited space, one example will be given. Claim 11 recites "wherein said adapter is removably slidable within said lumen of said catheter. As discussed above, element 10b is fixed to the catheter and thus cannot be said to be *removably slidable* and element 60 is too large to fit within catheter 10 and thus cannot be removably slidable *within* said lumen of said catheter.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
GERALD HELLER et al.

By their attorney,

Date: _____

September 8, 2009



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